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John C. Opie

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PHOENIX, AZ 85004-4498

EXAMINER

ANDERSON, GREGORY A

ART UNIT

PAPER NUMBER

3773

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,456

Applicant(s)

OPIE ET AL.

Examiner

GREGORY A. ANDERSON

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 28-33 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-24 and 28-33 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 03122008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 12, 17-18, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Eaves, III 6,143,008.

Regarding claim 1: Eaves, III discloses a device 10 for removing a tubular body member from a body, the device comprising a cutting tool that includes: a cutting head 20 having a leading edge 32 comprising an annular cutting blade 30 (Col. 7 ll. 17-24) and an attachment section (Fig. 1, left of reference number 25); and a body section 11 having a proximal end, a distal end, and an inner passage (Col. 5 ll. 38-40) therethrough, the distal end operable to couple the attachment section of the cutting head (Col. 5 ll. 14-27).

Regarding claim 2: Eaves, III discloses the cutting head further including an inner cavity 26 that is funnel-shaped (Col. 6 ll. 57-60) and having a first inner diameter at the leading edge and a second inner diameter (Fig. 1), the second inner diameter being smaller than the first inner diameter, the inner cavity compressing body tissue during operation of the cutting tool (Fig. 8, Col. 9 ll. 51-61).

Regarding claim 3: Eaves, III discloses the attachment section of the cutting head being threaded and the distal end of the body section is threaded, the cutting head attachable to the body section by threading it onto the distal end (Col. 5 ll. 14-27).

Regarding claim 4: Eaves, III discloses the body section being tubular (Fig. 1)

Regarding claim 7: Eaves, III discloses the body section having an exterior surface (Fig. 1) and a structure positioned on the exterior surface (Col. 9 ll. 62-64).

Regarding claim 12: Eaves, III further discloses the cutting head pivoting when attached to the body section (Col. 11 ll. 34-41).

Regarding claim 17: Eaves, III further discloses a handle 11 attached to the proximal end of the body section.

Regarding claim 18: Eaves, III discloses the handle is a cylindrical tube (Fig. 1).

Regarding claim 31: Eaves, III discloses a cutter head 20 used with a cutting tool for removing a tubular body member from a body comprising: a leading edge 32 comprising an annular cutting blade 30 (Col. 7 ll. 17-24); an inner cavity 21 extending therethrough, the inner cavity comprising a funnel-shaped section 27 having a first diameter juxtaposed the leading edge and a second diameter, the second diameter being smaller than the first diameter (Fig. 7); and an attachment structure for attaching to a body section (Col. 5 ll. 14-27).

Regarding claim 32: Eaves, III discloses a cutting tool for removing a tubular body member from a body, the cutting tool comprising: a cutting head 20; and a body section 11 connectable to the cutter head, the body section having an exterior surface (Fig. 1) and a structure positioned on the exterior surface (Col. 9 ll. 62-64).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Lambert 4,666,437.

Eaves, III discloses the invention essentially as claimed above.

However, Eaves, III does not disclose the exterior surface of the body section including a hydrophilic coating.

Lambert discloses a hydrophilic coating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the hydrophilic coating of Lambert in order to give good hand grip in dry conditions while simultaneously becoming very slippery when in contact with body liquids as taught by Lambert (Col. 1 ll. 14-26).

5. Claims 6, 9-11, 20-23, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Taheri 5,634,935.

Regarding claim 6: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose the exterior surface of the body section coated with a low-friction coating.

Taheri discloses coating the instrument with a low-friction coating (Col. 4 ll. 46-51).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the low-friction coating of Taheri in order to provide ease of movement of the instrument as taught by Taheri (Col. 4 ll. 46-51).

Regarding claims 9-11: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose an endovascular component. Eaves, III further does not disclose the endovascular component comprising a flexible tube and a medical guide wire. Eaves, III further does not disclose the endovascular component including one or more structures to which the tubular body member can be attached.

Taheri discloses endovascular component 31, 32 comprising a flexible tube and medical guide wire (Col. 3 ll. 36-47) and including one or more structures (balloon, Col. 3 l. 45) to which the tubular body member can be attached.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the endovascular component of Taheri in order to permit the internal visualization of the veins as taught by Taheri (Col. 3 ll. 37-47).

Regarding claim 20: Eaves, III discloses a cutting tool comprising: a tubular body section 11; a cutting head 20 attached to the tubular body section, the cutting head having a leading edge 32 comprising an annular cutting blade 30 (Col. 7 ll. 17-24); and

an opening extending through the cutting tool (Fig. 1); wherein the opening is sized to allow the tubular body member and some body tissue surrounding the tubular body member to fit inside.

However, Eaves, III does not disclose an endovascular component having a diameter smaller than the diameter of the tubular body member, the endovascular component being capable of being inserted into the tubular body member.

Taheri discloses an endovascular component 31, 32 having a diameter smaller than the diameter of the tubular body member, the endovascular component being capable of being inserted into the tubular body member.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the endovascular component of Taheri in order to permit the internal visualization of the veins as taught by Taheri (Col. 3 ll. 37-47).

Regarding claims 21 and 22: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose an endovascular component including an inner and an outer component and the inner component being a medical guide wire.

Taheri discloses an inner 32 and outer component 31 and the inner component comprising a medical guide wire (Col. 3 ll. 36-47).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the inner and outer components of

Taheri in order to permit the internal visualization of the veins as taught by Taheri (Col. 3 II. 37-47).

Regarding claim 23: Eaves, III further discloses a torque handle coupled to the tubular body section (Col. 11 II. 38-42).

Regarding claim 28: Eaves, III discloses a method for removing a tubular body member from a body, the method comprising the steps of: making a first incision; accessing and dividing a first end of the tubular body member near the first incision; making a second incision; accessing and dividing a second end of the tubular body member near the second incision; positioning a cutting tool having a leading edge comprising an annular cutting blade and an inner cavity therethrough; advancing the cutting tool from the first end to the second end, the cutting tool cutting through and dissecting body tissue as it moves, wherein the tubular body portion is positioned within the dissected body tissue; and removing the dissected body tissue including the tubular body member (Col. 10 II. 47-67, Col. 11 II. 1-24).

However, Eaves, III does not disclose inserting an endovascular component into the first end of the tubular body member; moving the endovascular component through the tubular body member and out the second end so that the endovascular component has a proximal end exposed at the first end of the tubular body structure and a distal end exposed at the second end of the tubular body structure; and securing the proximal end of the endovascular component and the distal end of the endovascular component and straightening the tubular body member by applying force to each end of the endovascular component.

Taheri discloses inserting an endovascular component into the first end of the tubular body member; moving the endovascular component through the tubular body member and out the second end so that the endovascular component has a proximal end exposed at the first end of the tubular body structure and a distal end exposed at the second end of the tubular body structure; and securing the proximal end of the endovascular component and the distal end of the endovascular component and straightening the tubular body member by applying force to each end of the endovascular component (Col. 3 ll. 30-64).

Regarding claim 29: Eaves, III discloses the cutting tool is advanced by utilizing a twisting motion (Col. 11 ll. 38-41).

6. Claims 8, 14, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Fogarty et al. 5,968,066.

Regarding claim 8: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose the structure on the exterior surface is a helical thread.

Fogarty et al. discloses helical thread 23.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the helical thread of Fogarty et al. in order to form a better seal with the skin as taught by Fogarty et al. (Col. 3 ll. 64-67).

Regarding claim 14: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose the body section being polycarbonate.

Fogarty et al. discloses the body section being polycarbonate (Col. 8 ll. 27-30).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the polycarbonate of Fogarty et al. in order to facilitate observation by the operator.

Regarding claim 33: Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose the structure on the exterior surface is a helical thread.

Fogarty et al. discloses helical thread 23.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the helical thread of Fogarty et al. in order to form a better seal with the skin as taught by Fogarty et al. (Col. 3 ll. 64-67).

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Goldberg et al. 5,304,189.

Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose the cutter head comprised of steel.

Goldberg et al. discloses a steel cutting head (Col. 4 ll. 27-30).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the material of Goldberg in order to facilitate the safe use within the body of a patient of the device as taught by Goldberg (Col. 4 ll. 27-30).

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Hogendijk 6,080,175.

Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose an automatic advancement device comprising an ultrasonic vibrator or an electric motor.

Hogendijk discloses an automatic advancement device that comprises an ultrasonic vibrator 450 or an electric motor (Col. 9 ll. 43-44).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III with the ultrasonic vibrator or electric motor of Hogendijk in order to facilitate axial motion of the movement of the cutting tool.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Evans et al. 6,193,653.

Eaves, III discloses the invention essentially as claimed as discussed above.

However, Eaves, III does not disclose a hand grip attached to the handle.

Evans discloses a hand grip 14 attached to the handle.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the handle of Eaves, III with the hand grip of Evans in order to facilitate the use of only one hand to move the tool during the procedure as taught by Evans (Col. 5 ll. 65-67).

10. Claims 24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eaves, III in view of Taheri as applied to claims 20 and 28 above, and further in view of Hogendijk.

Regarding claim 24: Eaves, III in view of Taheri disclose the invention essentially as claimed as discussed above.

However, Eaves, III in view of Taheri does not disclose an automatic advancement device.

Hogendijk discloses an automatic advancement device (Col. 9 ll. 43-44)

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III in view of Taheri with the automatic advancement device of Hogendijk in order to facilitate axial motion of the cutting tool.

Regarding claim 30: Eaves, III in view of Taheri disclose the invention essentially as claimed as discussed above.

However, Eaves, III in view of Taheri does not disclose motor to advance the cutting tool.

Hogendijk discloses a motor to advance the cutting tool (Col. 9 ll. 43-44)

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eaves, III in view of Taheri with the motor of Hogendijk in order to facilitate axial motion of the cutting tool.

Response to Arguments

Applicant's arguments filed 24 April 2008 have been fully considered but they are not persuasive. Regarding clarification of "leading edge 32" or "22" Examiner intended edge to be "32" and has been corrected in the above rejection.

Regarding the argument that edge 32 is not a leading edge: the edge 32 of the Eaves device is a leading edge, in that it is the first edge to begin cutting the side branching vessels.

Regarding the argument that the groove of Eaves is not a structure positioned on the exterior surface: Examiner contends that a groove is in fact a structure that is on the surface of the device.

In response to applicant's argument that the groove of Eaves is for guiding a stapler not for advancing a cutting tool, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3773

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773